

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA

v.

**FLOYD A. BENKO,
Defendant**

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No. 1:15-cr-00159

(Judge Kane)

MEMORANDUM

Before the Court is the Government's motion in limine seeking a ruling that certain test result documents and a summary chart based on them will be admissible at trial. (Doc. No. 30.) The Court convened a hearing on the motion on August 17, 2016. The motion has been fully briefed and is ripe for disposition. For the reasons that follow, the Court will grant the Government's motion, except that exhibits 9, 10, and 24 must be introduced through a qualified witness at trial.

I. BACKGROUND

The present indictment alleges that Defendant Floyd Benko violated federal health care laws by intentionally deviating from Standard Operating Procedures (SOPs) during the performance of genetic tests for 124 oncology patients at Hershey Medical Center (HMC).¹ (See Doc. No. 1.)

In the motion, the Government seeks a pre-trial ruling as to Government's exhibits 8, 9, and 10. (Doc. No. 30-1 at 1.) At the hearing, the Government moved for the first time for the admission of several other exhibits; the present memorandum also concerns three of those: Government's exhibits 9A, 9B, and 24. Government's exhibit 8 is a summary chart purporting

¹ A more detailed explanation of the alleged events underlying the indictment can be found in the Court's prior memorandum, dated February 16, 2016. (See Doc. No. 32 at 1-4.)

to show the disagreement between the EGFR, KRAS, and/or BRAF assays that Defendant performed and the assays performed for the same patients by outside laboratories. (Doc. No. 30-1 at 1-2.) At the hearing, the Government introduced the testimony of Dr. Thomas Abendroth, the HMC physician who compiled the chart. (Id.)

The data used to compile Government's exhibit 8 chart were taken from the original diagnostic test results, which form part of the exhibits that have been marked as Government's exhibits 9, 9A, and 9B. (Id.) Exhibit 9 contains the test result documents from HMC itself, including technical printouts, result reports, and notations from HMC staff including Defendant.

Exhibits 9A and 9B are the assay results and documentation from the two outside laboratories, NeoGenomics Laboratories and Central Pennsylvania Alliance Labs, LLC (CPAL). (Id. at 2.) According to the Government, NeoGenomics performed the tests in Fort Meyers, Florida, though the documents seem to suggest that NeoGenomics performed the tests in Irvine, California. (Id.) CPAL is based in York, Pennsylvania. (Id. at 2.) The exhibits also include a spreadsheet of results and supporting documentation from each laboratory for each test they performed.

Exhibit 10 does not appear to contain new information or documentation; instead exhibit 10 combines the diagnostic results from exhibits 9, 9A, and 9B and sorts them according to the affected patient. Exhibit 24 is comprised of the amended HMC patient files for the affected patients reflecting that re-testing was performed for the patients and indicating the new results.

II. LEGAL STANDARD

The Government filed the motion in limine seeking a pre-trial ruling that these exhibits are admissible. Defendant argues that the exhibits should be excluded because they violate the Confrontation Clause under Melendez-Diaz v. Massachusetts, 557 U.S. 305 (2009). The

Government's motion in limine is governed by jurisprudence related to the Confrontation Clause of the Sixth Amendment and by the Federal Rules of Evidence.

First, the Confrontation Clause guarantees a criminally accused defendant the right to confront witnesses against him. Melendez-Diaz, 557 U.S. at 309. In practice, the rule bars the introduction of hearsay testimony unless the prosecution calls the declarant-witness and presents him or her for cross-examination, or unless the witness is currently unavailable and the defendant previously had the opportunity to cross-examine the witness. Crawford v. Washington, 541 U.S. 35, 53-54 (2004). The Confrontation Clause does not operate to exclude evidence unless the evidence is "testimonial" in nature. Id. The Supreme Court has not announced a bright-line rule for determining whether or not evidence is "testimonial," but the "core class" of testimonial statements has been describes as "ex parte in-court testimony or its functional equivalent." Melendez-Diaz, 557 U.S. at 310 (quoting Crawford, 541 U.S. at 51-52)). Courts look to whether or not the out-of-court "statements ... were made under circumstances which would lead an objective witness reasonably to believe that the statement would be available for use at a later trial." Id. In the context of scientific testing, the Supreme Court has held that a criminally accused has the right to cross-examine the laboratory scientists who conducted tests used to establish facts against the defendant and who swear affidavits as to the test results. Melendez-Diaz, 557 U.S. at 312. However, the Confrontation Clause only applies to testimonial lab reports, that is, lab reports with the "primary purpose" of "creat[ing] a record for trial." Michigan v. Bryant, 562 U.S. 344, 358 (2011) (Sotomayor, J.). "Where no such primary purpose exists, the admissibility of a statement is the concern of state and federal rules of evidence, not the Confrontation Clause." Id. at 359.

In addition to constitutional concerns, the admissibility of diagnostic tests and summaries of diagnostic tests is governed by Federal Rules of Evidence 803(6) and 1006. Rule 803(6), which embodies the so-called “business records” hearsay exception, provides a hearsay exception for “records of a regularly conducted activity.” See Fed. R. Evid. 803(6). A record “of an act, event, condition, opinion, or diagnosis” qualifies under the exception if:

(A) the record was made at or near the time by--or from information transmitted by--someone with knowledge; (B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit; (C) making the record was a regular practice of that activity; (D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and (E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

Fed. R. Evid. 803(6). Once records are deemed admissible under Rule 803(6), the synthesis of that data into an admissible chart or summary is governed by Federal Rule of Evidence 1006. Rule 1006 provides that “voluminous writings, recordings, or photographs that cannot be conveniently examined in court” may be presented in the form of a summary, chart, or calculation. Fed. R. Evid. 1006. The originals or true copies must be available to the other litigants, and a court may order that the originals be introduced in addition to the summary, if necessary. Id.

III. DISCUSSION

a. Confrontation Clause

The first question for purposes of the Government’s motion is whether or not the test result documents are “testimonial,” so as to implicate the Confrontation Clause. If the reports are testimonial, then they are inadmissible unless the Government calls those who performed the tests as witnesses subject to cross examination. See Crawford, 541 U.S. at 51-52.

The Supreme Court has addressed the admissibility of scientific test results over Confrontation Clause objections. In Melendez-Diaz, the majority held that the defendant had the right to cross examine the forensic analysts who were responsible for identifying cocaine in a physical exhibit. 557 U.S. at 312-13. In that case, the forensic tests were unquestionably “testimonial,” because they were performed pursuant to state law with the obvious purpose of establishing facts against the defendant. See id. at 309-11. In a similar case, Bullcoming v. New Mexico, a majority of the Supreme Court held that the defendant accused of drunk driving had the right to cross-examine the forensic analysts who had analyzed his blood alcohol content. 131 S.Ct. 2705 at 2717-19. Justice Sotomayor concurred in the result but wrote separately to identify scenarios involving laboratory results that may not implicate the Confrontation Clause, citing her own majority opinion in Michigan v. Bryant, another Confrontation Clause decision from 2011. Id. at 2722-23. Justice Sotomayor described four such scenarios: (1) where the state could suggest an alternate primary purpose for the scientific report, other than to establish an evidentiary fact against the defendant; (2) where the state is able to present as a witness a “supervisor, reviewer, or someone else with a personal ... connection to the scientific test at issue;” (3) where an expert witness testifies independently about test results not otherwise offered into evidence; and (4) where the test results were “only machine-generated,” such as a computer printout. Id. at 2722.

In the present case, the Court finds that the laboratory test results are not testimonial and do not implicate the Confrontation Clause. Here, the Government has demonstrated an alternate primary purpose for the test results. At the hearing, Dr. Thomas Abendroth testified that HMC contacted outside laboratories to perform re-testing of Defendant’s assays as a quality control measure after a physician discovered that the results Defendant obtained were not consistent with

the relevant patient's clinical profile. HMC tasked Dr. Abendroth with obtaining correct test results for the affected patients in order to notify their treating physicians and take corrective action. Defense counsel did elicit testimony from the witness that HMC contacted the local police department after learning of the widespread inconsistencies in testing, however Dr. Abendroth was not working with law enforcement. The outside lab results were returned to HMC, not criminal investigators. The results were shared with treating physicians, compiled into a summary chart, and eventually passed into the possession of law enforcement. Despite some police involvement, the Court finds that the "primary purpose" of the lab results obtained by CPAL and NeoGenomics and transmitted to HMC was not to create a record for trial. The primary purpose of the documents was clinical. Accordingly, the Confrontation Clause is not implicated, and the admissibility of the test results is governed only by the Federal Rules of Evidence.

b. Federal Rules of Evidence

The next question for the Court is whether all of the requirements of the hearsay exception have been fulfilled so that the test results are admissible under the Federal Rules of Evidence. As a threshold matter, there is little doubt that the diagnostic test result documents are hearsay material, because each of them provides the statement of an out-of-court forensic analyst offered for the truth of the matter asserted, *i.e.*, the test result obtained. See Fed. R. Evid. 803. Neither party has argued the contrary.

Federal Rule of Evidence 803(6), the business records exception, provides that records that are hearsay material may nevertheless be admitted into evidence if they are "records of a regularly conducted activity." Fed. R. Evid. 803(6). As noted above, there are five foundational requirements to invoke the exception. Id. First, the record must have been made

contemporaneously with the action or event it purports to record. Id. Second, the record must be “kept in the course of a regularly conduct activity” of a business or organization. Id. Third, the business or organization must regularly make records of this type. Id. Fourth, the record must be authenticated either by a competent witness familiar with the business or organization’s recordkeeping or by a certification in compliance with Federal Rule of Evidence 902. Id. Pursuant to Rule 902, a records custodian or other qualified person from the business or organization may provide a certification attesting to the record’s compliance with Rule 803(6) in lieu of appearing at trial. Fed. R. Evid. 902(11). Finally, if other circumstances suggest that a record is unreliable, then it may be excluded even if it technically satisfies the rule’s other requirements. Fed. R. Evid. 803(6).

The Court finds that the requirements of Rule 803(6) have been satisfied. At the hearing, the Government introduced the testimony of Dr. Jeffrey Wisotzkey of CPAL, who testified to each of the foundational elements of the business records exception. See United States v. Pelullo, 964 F.2d 193, 201 (3d Cir. 1992). Further, the Government has presented the Court with a signed certification from Cheri Copie, who attests under penalty of perjury that she is the Chief of Compliance for NeoGenomics and that the test results transmitted to HMC from NeoGenomics satisfy the requirements of Rule 803(6). See Fed. R. Evid. 902(11). Consequently, the Court finds that the rule’s requirements have been satisfied, and the Government’s proffered exhibits 9A and 9B are admissible.

Finally, the Court finds that Government’s exhibits 9, 10, and 24, comprised of HMC test results and patient files amended to reflect the results of the assays performed by outside laboratories, will be admissible at trial provided that the Government introduce the exhibits through the testimony of a someone with personal knowledge or a qualified employee or record

keeper as required by the Federal Rules of Evidence. At the hearing, Dr. Keri Donaldson testified that he amended the HMC patient files to reflect the test results from outside laboratories, but no witness formally testified as to the foundational requirements of the original test result printouts or the patient records Dr. Donaldson amended. Provided that the Government calls a competent witness to lay a proper foundation, exhibits 9, 10, and 24 will be admitted.

Finally, the Court finds that the summary chart marked as Government's exhibit 8 is also admissible as a summary of the HMC results compared to those of the outside laboratories.² Federal Rule of Evidence 1006 provides that summaries are admissible when, due to its voluminous nature, other documentary evidence cannot conveniently be presented at trial. Fed. R. Evid. 1006. The HMC patient files and the test reports from CPAL and NeoGenomics are together several hundred pages long and contain information that is not salient to the present prosecution. Consequently, the Court will admit the summary document. To the extent that Defendant's objection to the summary is based on the Confrontation Clause, the Court has found in this memorandum that the source materials for the summary chart, i.e., the outside lab reports and the HMC patient files, are not subject to the Confrontation Clause. Further, the Government introduced the testimony of Dr. Abendroth who prepared the summary chart, and defense counsel cross-examined him. Consequently, the Confrontation Clause cannot operate to bar the summary chart's introduction.

² The admissibility of exhibits 8 and 10 is contingent upon the proper introduction of exhibit 9 because exhibit 9 provides some of the underlying data summarized in exhibit 8 and combined with the outside diagnostic test results in exhibit 10.

IV. CONCLUSION

For the foregoing reasons, the Court will grant the Government's motion except insofar as exhibits 9, 10, and 24 must be introduced at trial through a qualified individual at trial. An order consistent with this memorandum follows.